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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
1422-0625P

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/790,730	March 03, 2004

First Named Inventor: Makoto OZEKI

Art Unit	Examiner
1627	D. CLAYTOR

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 42874.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Craig A. McRobbie

Typed or printed name

703-205-8000

Telephone number

MAR 15 2012

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

Docket No.: 1422-0625P
(Patent)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of:
Makoto OZEKI et al.

Application No.:	10/790,730	Confirmation No.:	2621
Filed:	March 03, 2004	Art Unit:	1627
For:	PHARMACEUTICAL COMPOSITION FOR TREATING MOOD DISORDERS	Examiner:	D. CLAYTOR

ARGUMENTS IN SUPPORT OF PRE-APPEAL BRIEF REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Final Office Action dated November 17, 2011 and the Advisory Action dated February 28, 2012, Applicants respectfully request a pre-appeal brief conference. This request is being concurrently filed with a Notice of Appeal.

Status of the Claims

Claims 5, 7, and 13-14 are pending in the above-identified application. Applicants request withdrawal of the rejections of record as being clearly erroneous in fact and in law for the reasons set forth below.

Issues under 35 U.S.C. § 103(a)

Claims 5, 7, and 13-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ueda et al. '103 (US 6,831,103) in view of Hamilton (J. Neurol. Neurosurg Psychiat, 1960, 23, 56). Applicants respectfully traverse. Reconsideration and withdrawal of this rejection are respectfully requested based on the following considerations.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

(a) determining the scope and content of the prior art;

(b) ascertaining the differences between the prior art and the claims in issue;

(c) resolving the level of ordinary skill in the pertinent art; and

(d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* MPEP 2143.03.

The Present Invention

Independent claim 5 recites:

> A method for treating an individual having at least symptoms of feelings of guilt, suicide, and retardation: psychomotor, associated with a mood disorder, each symptom being assessed according to the assessment method by the Hamilton scale, comprising
>
> administering an effective amount of a composition comprising theanine to the individual in need of treatment, sufficient to reduce a score of the Hamilton scale,
>
> wherein said mood disorder is distinct from mood disorders associated with menstruation; and
>
> wherein said individual is a normofolatemic patient.

Dependent claim 7 is directed to an embodiment of claim 5 wherein said composition is administered as a food or beverage. Dependent claim 13 is directed to an embodiment of claim 5 wherein said normofolatemic patient shows a normal folate plasma level of from 3 to 17 ng/ml. Dependent claim 14 is directed to an embodiment of claim 5 wherein the content of theanine in the composition is 0.08 to 99% by weight of the composition.

Distinctions over the Cited References

As shown above, the present invention recites that at least three symptoms of feelings of guilt, suicide, and retardation: psychomotor are treated by theanine. This feature is not disclosed by Ueda et al. '103. Also, in the assessment for depression regarding 21 items (symptoms) with the Hamilton scale, a statistically significant effect was shown at Day 7 for only five symptoms, including the claimed three symptoms, among the 21 symptoms (see Table 1 of the present specification; *reproduced below from the printed publication of the present specification for the Examiner's convenience*). The cited references fail to disclose that at least the three symptoms among the 21 symptoms can be treated while showing effectiveness with statistical significance. When theanine is administered in Ueda et al. '103, one of ordinary skill in the art would not expect that only specific symptoms are improved when improvement in many symptoms of depression are not shown by the Hamilton scale.

TABLE 1

	Group Administered with Theanine-Formulated Tablet			
Items	Before Intake	Day 7	Day 14	Day 21
1. Depressed Mood	2.833 ± 0.322	2.000 ± 0.389**	1.083 ± 0.336**	0.583 ± 0.288**
2. Feelings of Guilt	2.667 ± 0.333	2.000 ± 0.369*	1.250 ± 0.351**	0.833 ± 0.322**
3. Suicide	2.750 ± 0.372	2.000 ± 0.369*	1.167 ± 0.322**	0.667 ± 0.333**
4. Insomnia Early	0.333 ± 0.142	0.583 ± 0.149	0.583 ± 0.163	0.583 ± 0.193
5. Insomnia Middle	0.250 ± 0.131	0.333 ± 0.142	0.500 ± 0.195	0.583 ± 0.193
6. Insomnia Late	0.250 ± 0.131	0.250 ± 0.131	0.667 ± 0.188	0.583 ± 0.149*
7. Work and Activities	0.917 ± 0.260	1.167 ± 0.241	0.917 ± 0.229	1.000 ± 0.213
8. Retardation: Psychomotor	2.833 ± 0.207	1.917 ± 0.288**	1.250 ± 0.351**	0.833 ± 0.345**
9. Agitation	0.917 ± 0.193	1.000 ± 0.174	1.000 ± 0.174	0.917 ± 0.149
10. Anxiety(Psychological)	0.833 ± 0.241	0.833 ± 0.207	1.000 ± 0.213	1.000 ± 0.213
11. Anxiety Somatic	0.833 ± 0.297	0.750 ± 0.279	0.833 ± 0.271	0.750 ± 0.218
12. Somatic Symptoms (Gastrointestinal)	0.417 ± 0.193	0.500 ± 0.195	0.500 ± 0.151	0.667 ± 0.142
13. Somatic Symptoms General	0.917 ± 0.260	0.833 ± 0.241	0.583 ± 0.193	0.583 ± 0.193
14. Genital Symptoms	0.417 ± 0.229	0.500 ± 0.230	0.417 ± 0.229	0.500 ± 0.230
15. Hypochondriasis	1.333 ± 0.256	1.250 ± 0.279	1.250 ± 0.279	1.167 ± 0.241
16. Diminished Insight	1.667 ± 0.188	1.083 ± 0.260*	0.417 ± 0.229**	0.333 ± 0.225**
17. Loss of Weight	1.083 ± 0.193	1.000 ± 0.246	1.000 ± 0.213	0.917 ± 0.193
18. Diurnal Variation - Morning or Evening	0.500 ± 0.195	0.583 ± 0.193	0.417 ± 0.149	0.500 ± 0.151
19. Depersonalization and Derealization	0.833 ± 0.207	0.750 ± 0.218	0.750 ± 0.218	0.750 ± 0.218
20. Paranoid Symptoms	1.083 ± 0.260	1.083 ± 0.229	0.833 ± 0.241	0.750 ± 0.218
21. Obsessional and Compulsive Symptoms	0.500 ± 0.195	0.583 ± 0.193	0.583 ± 0.193	0.583 ± 0.149

	Group Administered with Control Tablet			
Items	Before Intake	Day 7	Day 14	Day 21
1. Depressed Mood	2.833 ± 0.241	2.333 ± 0.188	2.000 ± 0.302	2.417 ± 0.193
2. Feelings of Guilt	2.167 ± 0241	2.250 ± 0.250	2.417 ± 0.229	2.083 ± 0260
3. Suicide	1.917 ± 0.358	1.833 ± 0.366	2.083 ± 0.260	2.083 ± 0.229
4. Insomnia Early	0.250 ± 0.179	0.333 ± 0.188	0.250 ± 0.179	0.250 ± 0.179
5. Insomnia Middle	0.167 ± 0.167	0.083 ± 0.083	0.167 ± 0.112	0.083 ± 0.083
6. Insomnia Late	0.083 ± 0.083	0.167 ± 0.112	0.250 ± 0.131	0.167 ± 0.112
7. Work and Activities	1.917 ± 0.149	1.917 ± 0.193	1.583 ± 0.149	1.750 ± 0.131
8. Retardation: Psychomotor	2.250 ± 0.218	2.083 ± 0.260	1.917 ± 0.313	2.083 ± 0.336
9. Agitation	0.500 ± 0.195	0.667 ± 0.225	0.583 ± 0.229	0.583 ± 0.260
10. Anxiety(Psychological)	1.083 ± 0.260	1.083 ± 0.260	0.833 ± 0.241	1.000 ± 0.246
11. Anxiety Somatic	1.167 ± 0.241	1.000 ± 0.246	0.833 ± 0.241	0.750 ± 0.250
12. Somatic Symptoms (Gastrointestinal)	0.417 ± 0.193	0.583 ± 0.229	0.583 ± 0.229	0.333 ± 0.188
13. Somatic Symptoms General	0.417 ± 0.193	0.333 ± 0.188	0.417 ± 0.193	0.333 ± 0.188
14. Genital Symptoms	0.500 ± 0.195	0.333 ± 0.188	0.333 ± 0.188	0.417 ± 0.193
15. Hypochondriasis	1.750 ± 0.218	1.500 ± 0.230	1.500 ± 0.195	1.417 ± 0.229
16. Diminished Insight	1.500 ± 0.151	1.197 ± 0.193	1.417 ± 0.193	1.417 ± 0.193
17. Loss of Weight	1.083 ± 0.229	1.000 ± 0.246	1.000 ± 0.246	1.083 ± 0.229
18. Diurnal Variation - Morning or Evening	0.833 ± 0.241	1.000 ± 0.246	0.917 ± 0.229	0.917 ± 0.229
19. Depersonalization and Derealization	1.250 ± 0.279	1.250 ± 0.218	1.417 ± 0.229	1.333 ± 0.188
20. Paranoid Symptoms	1.833 ± 0.297	1.750 ± 0.250	1.500 ± 0.195	1.167 ± 0.207
21. Obsessional and Compulsive Symptoms	0.750 ± 0.218	0.833 ± 0.271	1.000 ± 0.213	1.000 ± 0.275

Student paired t-test: vs. before intake
*p < 0.05
**p < 0.01

As stated in *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007), "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Furthermore, the mere fact that references ***can*** be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *Id.* As described above, Applicants have shown that the present invention achieves unexpected and unpredictable results.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Ueda et al. '103 in view of Hamilton fail to disclose all of the claim limitations of independent claim 5, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious.

Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

Dated: MAR 15 2012

Respectfully submitted,

By _____

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